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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/965,473      | 09/26/2001  | Terry A. Guinan      | P1046 US            | 2802             |

7590 02/14/2003  
Medtronic AVE, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403

EXAMINER

BAXTER, JESSICA R

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/965,473

Applicant(s)

GUINAN ET AL. 

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Information Disclosure Statement*

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 6, 7, 10, 11, 12, 13, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,048,350 to Vrba.

Regarding claims 1, 6, 7, 10 and 11, Vrba discloses a catheter comprising an elongate shaft (shaft 12) and a balloon having a flexible wall (balloon 16), an intermediate body (16B), proximal and distal cones (16A and 16C), proximal and distal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (FIG. 2 spaces 22), and a balloon expandable stent (stent 20).

Regarding claim 2, Vrba discloses that the circumferential groove has a shape selected from the C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 2 spaces 22).

Regarding claims 4, 12, 13 and 18, Vrba discloses that the at least one circumferential groove is at least partially filled with a flexible material that is adhered to the balloon (Column 3 lines 53-62).

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Regarding claim 15, Vrba discloses a method comprising the steps of providing a catheter having an elongate shaft (shaft 12), mounting a balloon around a distal end of the shaft, collapsing the balloon around the catheter shaft (FIG. 1 and Column 3 lines 24-36), and mounting a balloon expandable stent in a radially compressed configuration around the intermediate body of the balloon (Column 3 lines 29-36).

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,545,132 to Fagan et al.

Fagan discloses a balloon having a flexible wall, an intermediate body (balloon 12), proximal and distal cones (cones 18 and 20), proximal and distal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (groove 16), the groove having a shape selected from C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 1 groove 16), and wherein the diameters measured distal and proximal to the at least one circumferential groove are uneven (FIG. 3 end near cone 20).

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8, 9, 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No. 5,935,135 to Bramfitt et al.

Vrba discloses the claimed invention except for the cones having a larger deflated diameter than the deflated intermediate portion of the balloon. Bramfitt teaches that the enlarged cone

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sections are provided to restrain movement of the stent without changing the overall profile of the delivery system, preventing damage of the balloon by the stent, eliminating the biocompatibility problems of adhesives and the retractibility of protective sheaths (Column 2 lines 8-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent delivery system of Vrba with enlarged cone sections of Bramfitt in order to restrain the movement of the stent during delivery without changing the delivery system's overall profile, preventing damage to the balloon by the stent, eliminating biocompatibility problems associated with adhesives, and eliminating problems associated with the retractibility of a protective sheath.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba '350 in view of U.S. Patent No.6,254,608 to Solar. Vrba discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath (Column 3 line 44 – Column 4 line 2 and Column 5 lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon catheter of Vrba with the foamed material of Solar in order to protect the anatomical passageways during stent delivery and prevent the stent from slipping off the balloon without the use of a protective sheath.

### *Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to similar balloon catheters:

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U.S. Patent No. 3,810,474 to Cross

U.S. Patent No. 5,910,102 to Hastings

U.S. Patent No. 5,320,605 to Sahota

U.S. Patent No. 6,059,713 to Urick et al.

U.S. Patent No. 5,484,411 to Inderbitzen et al. U.S. Patent No. 6,280,412 to Pederson, Jr. et al.

U.S. Patent No. 5,728,068 to Leone et al.

U.S. Patent No. 6,302,893 to Limon et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

  
jrb

February 4, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700